ACAP
Association for Community Affiliated Plans

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Christopher D. Palmieri, Chair | Margaret A. Murray, Chief Executive Officer

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Danny Werfel, Commissioner
Internal Revenue Service
Department of the Treasury

Lisa Gomez, Assistant Secretary
Employee Benefits Security Administration
Department of Labor

Ellen Montz, Deputy Administrator and Director
Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services
Department of Health & Human Services

Submitted electronically via: www.regulations.gov

RE: Federal Register Number 2023-21969, File Code 1210–ZA31, Request for Information; Coverage of Over-the-Counter Preventive Services

Dear Commissioner Werfel, Assistant Secretary Gomez, and Deputy Administrator and Director Montz:

The Association for Community Affiliated Plans (ACAP) thanks you for the opportunity to comment on the request for information, "Coverage of Over-the-Counter Preventive Services" (the "RFI") issued by the Departments of Health and Human Services, Labor, and the Treasury (the "Departments").

ACAP is an association of 80 not-for-profit, community-based Safety Net Health Plans (SNHPs). Our member plans provide coverage to more than 25 million individuals enrolled in Medicaid, the Children's Health Insurance Program (CHIP), Medicare Special Needs Plans for dually-eligible individuals, the Basic Health Program, and the ACA Marketplaces. Nationally, Safety Net Health Plans serve almost half of all Medicaid managed care enrollees. Of ACAP's Safety Net Health Plan Members and Partner Plans, 27 offer qualified health plans (QHPs) serving approximately 950,000 enrollees in the Marketplaces.

ACAP appreciates the Administration's desire to ensure that all preventive services to which section 2713 of the Public Health Service Act applies are covered without cost-sharing by non-grandfathered group or individual health insurance coverage and non-grandfathered group health plans. In general, we ask that any potential federal policy changes related to this RFI be specifically tailored as appropriate for each applicable OTC preventive item or service, as there are different factors that come into play with each product. For example, there is still much unknown about new OTC contraceptive products coming to market. By contrast, naloxone

spray is dispensed in relatively exigent circumstances with respect to a narrower and often-underserved population. Accordingly, our comments primarily focus on specific OTC product examples and reference those specific products accordingly throughout. We ask that the Departments avoid drawing broad inferences from a recommendation that is specific to one product and carefully consider the facts and circumstances surrounding each OTC preventive product to which section 2713 may apply. We welcome additional discussion with the Departments regarding a broader swath of products than those that we reference.

As explained in more detail in this letter, as the Departments consider future policy changes, we recommend that the Departments permit plans and issuers to maintain important utilization management and cost-containment measures given the distinguishing features of this specific item and to retain affordable plans for all health insurance consumers. Finally, we wish to emphasize the need to provide sufficient lead time—at least one year from any relevant implementing guidance—to accommodate necessary system changes by plans, issuers, and retailers alike.

Expanded Comments

A. Access to and Utilization of OTC Preventive Products

In general, among all ACAP plans today, OTC products that are covered without cost-sharing pursuant to section 2713, such as breast pumps and tobacco cessation pharmacotherapy, require a prescription and the use of in-network providers, and are subject to reasonable utilization management techniques. Each of these plan design features plays an important role in ensuring quality and affordability for enrollees in the plan.

First, a prescription ensures that the enrollee interacts with a medical provider not only to receive appropriate counseling for the product on hand but to also receive other medically appropriate items and services during an interaction. In the context of tobacco cessation, for which federal guidance permits a prescription requirement for coverage,[1] this touchpoint allows the provider to inquire about tobacco use in the first place and for individuals who use tobacco to be screened, according to clinical guidelines, for certain chronic conditions or cancers where their risk factors are elevated. In the context of OTC contraceptives, this touchpoint is important for those individuals of child-bearing age who may not interact otherwise with their medical provider but for renewing (or changing) their contraceptive prescription. Therefore, we urge the Departments to extend current guidance that allows plans and issuers to require a prescription for non-emergency OTC contraceptives.[2] A prescription would be issued by any medical provider, including a pharmacist, authorized to

[1] Q5, FAQs about Affordable Care Act Implementation Part 19, May 2, 2014, available at: https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/aca_implementation_faqs19
[2] See Q5, FAQs about Affordable Care Act Implementation Part 54, July 28, 2022, available at: https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf

write the prescription and be the basis to adjudicate a claim efficiently for the OTC contraceptive. If a prescription were not required, it would be difficult for plans and issuers to ensure that the products are being purchased for, and needed by, the covered individual. A prescription also allows the medication to be documented in the individual's medical record, which in turn allows for medication reconciliation and safety alerts for potential contraindications the provider can review.

Second, limiting $0 cost-sharing for non-emergency OTC contraceptives to a network pharmacy is an important mechanism to prevent fraud, waste, and abuse and avoid price gouging. Typically, a plan's pharmacy network is broad, with a range of local and mail order pharmacy options. When necessary, plans and issuers also allow an individual to receive preventive items and services from an out-of-network provider at no cost-sharing pursuant to section 2713 if an in-network provider is not available. The use of a provider network allows plans and issuers to encourage members to obtain covered items and services at a cost-effective negotiated rate, which helps to mitigate premium growth for all members of the plan (and in turn, reduces federal government tax credit expenditures for applicable qualified health plans). ACAP is concerned that a coverage mandate for plans and issuers to cover any OTC contraceptive claim from any pharmacy would disincentivize providers from accepting reasonable negotiated rates and may cause friction at the point of sale for consumers if the claim cannot be processed. Limiting coverage to an (often broad) network of providers better ensures that the OTC contraceptive claim will be processed accurately and completely so that the member incurs $0 cost-sharing as intended. Moreover, given that at the time of this comment submission, we lack any information about the future retail price of the *Opill*, a "blanket" coverage mandate for all out-of-network contraceptives creates even more uncertainty from an actuarial and rate-setting perspective. It would be difficult to predict the costs associated with this policy change given the potential for excessive price gouging. Based on our past experience, small entities like SNHPs would find it difficult to lower price markups.

Similarly, applying reasonable medical management techniques like a formulary and frequency limits is particularly important for covered OTC contraceptive products and many other OTC preventive services. Applying these techniques helps to prevent potential overbilling and unsafe utilization—for example, utilizing a drug in excess of the product's dosing guidelines. For example, it may be unsafe to prescribe a specific tobacco cessation pharmacotherapy for a given individual as all seven FDA-approved medications have specific contraindications, warnings, precautions, other concerns, and side effects, according to the clinical guidelines.[3] We ask the Departments to continue apply existing regulations that allow plans and issuers to apply "reasonable medical management techniques to determine the frequency, method, treatment, or setting" for an OTC product "to the extent not specified in the relevant recommendation or guideline;" and to the extent not specified in a recommendation or

[3] See Table 3.2 of Tobacco Use and Dependence Guideline Panel. Treating Tobacco Use and Dependence: 2008 Update. Rockville (MD): US Department of Health and Human Services; 2008 May. 3, Clinical Interventions for Tobacco Use and Dependence. Available from: https://www.ncbi.nlm.nih.gov/books/NBK63948/

guideline, allow a plan or issuer to "rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service."[4] This would allow for reasonable limits on fulfillment of an OTC product according to the specific clinical guidelines for the product. It would also be prudent in the long-term to allow plans and issuers to continue to retain the ability to design a formulary to prefer, for example, a generic or private-label OTC product at $0 cost-sharing. In this scenario, a branded product may be covered on a different formulary tier with additional cost-sharing. Alternatively, a plan or issuer would cover the branded product off-formulary through an easily accessible, transparent, and sufficiently expedient exceptions process for a covered individual to obtain the branded OTC product as prescribed by their provider.

B. Implementation Issues

As explained above, a prescription is a critical component to facilitate health care quality and efficient claims adjudication. However, if a prescription were not required, several operational challenges would arise in connection with insurer (and third-party administrator) billing systems. For example, for pharmacies to submit a clean claim for any medication today, one ACAP plan notes the pharmacy must include both a National Provider Identifier (NPI) and a CPT code on the claim. We note similar approaches were taken during the period in which $0 coverage of COVID-19 tests was required: a pharmacist would use their own national provider identifier (NPI) number, pharmacy NPI number, or dummy NPI depending on the plan and state protocol.[5] A CPT code is an important data point for system processing to identify the test itself on the claim. The CPT code is particularly important to identify specifically the product being dispensed and quantity limits under the plan—an important consideration given the prescriptiveness of many guidelines applicable to the wide range of preventive items subject to section 2713. Indeed, one plan found that pharmacists regularly included several $0 COVID tests when filling a different prescription, without prompting by the beneficiary. The lack of reasonable controls on quantities and medical necessity for such COVID-19 tests led to subsequent changes by the relevant payer to put in place quantity limits. Even when these monthly quantity limits were put into place for the COVID-19 tests, there were countless anecdotal accounts from consumers whose pharmacy would distribute the maximum number of monthly tests every time they picked up a monthly prescription (regardless of whether the consumer requested them).

These operational considerations underscore the importance of giving plans and issuers sufficient lead time to make necessary billing system accommodations to process OTC products

[4] 45 CFR 147.130(a)(4).

[5] KFF, "Insurance Coverage of OTC Oral Contraceptives: Lessons from the Field," Sept. 14, 2023, available at: https://www.kff.org/report-section/insurance-coverage-of-otc-oral-contraceptives-lessons-from-the-field-report/. One ACAP plan notes a dummy NPI was created by the government for use in Medicaid claim in the context of COVID-19 tests billed by a pharmacy.

without a prescription. Specifically, ACAP urges the Departments to provide for a minimum of one year of lead time after the date on which a new federal coverage mandate specifically addressing OTC contraceptives is issued to implement any new requirement starting with the plan or policy year that begins on or after the date that is one year after the new federal guidance is issued. We note that this timeframe is generally consistent with the timeline required under 45 CFR 147.130(b)(1), the implementing regulation for section 2713. If plans and issuers are unable to make billing system changes to adjudicate claims without a prescription at the point-of-sale, we ask that the Departments exercise enforcement discretion (or similar flexibility like a phased-in implementation period) to allow plans and issuers to satisfy their obligations by accepting claims from members for reimbursement. While we acknowledge that direct member reimbursement has a greater potential to cause members to incur out-of-pocket costs, in the OTC context, it has been an established pathway for covered OTC products, such as breast pumps and COVID-19 tests purchased directly by the member.

C. Health Equity

ACAP firmly believes in the importance of reducing racial and ethnic health disparities and is committed to improving health equity in the spirit of its mission to strengthen Safety Net Health Plans in their work to improve the health of low-income individuals and people with significant health needs. Unfortunately, due to the lack of complete race and ethnicity and other data associated with health disparities particularly for consumers insured through group and individual health insurance coverage, we cannot ascertain whether certain populations would be disproportionately affected by a federal policy change regarding access to $0 OTC contraceptives or other OTC preventive services. We do, however, have concerns that requiring the blanket coverage of these products without a prescription, reasonable medical management, or the use of a network provider will be counterproductive to some of the Administration's efforts to close care gaps for underserved populations. These individuals could receive sub-par health care, for example, if their contraceptive choice is not documented in their medical record for review by a provider. Additionally, without a requirement for a prescription, these populations could be missing out on an opportunity to receive screenings, lab work and other preventive services appropriate to their age, health history, and demographic profile.

D. Economic Impacts

We appreciate the Departments' interest in understanding the economic impacts of OTC preventive services broadly including new-to-market OTC contraceptive products. Unfortunately, with respect to the latter, we cannot provide meaningful guidance for the questions posed in the RFI as we lack retail cost information for the *Opill* or other potential FDA approved contraceptive products. Regarding cost offsets associated with pregnancy avoidance, these offsets will not be known for several years—to the extent a plan realizes a cost offset for a preventive service, rarely will that offset occur in the same plan year. It would be helpful for

this analysis to receive federal guidance about the range of retailers through which covered contraceptive products can be purchased at $0 cost sharing. If the Departments dictate that the range of eligible retailers must be broader than network pharmacies to include any retailer of an OTC contraceptive product, despite the relative breadth of a typical plan's pharmacy network including mail order options, then it will be very difficult for the plan or issuer to establish reasonable controls on prices and quantities, much less for the retailer to verify insurance coverage to confirm the individual's eligibility.

Conclusion

ACAP thanks the Departments for your willingness to consider the aforementioned issues. If you have any additional questions or comments, please do not hesitate to contact Heather Foster (202-204-7508 or hfoster@communityplans.net).

Sincerely,

/s/

Margaret A. Murray
Chief Executive Officer